

- c. positioning the distal tip of the prosthesis cylinder for implantation;
and
- d. pulling the insertion tool and suture back out of the penis.

27. (Currently Amended) A method of implanting a penile prosthesis device without puncturing the glans penis or the penile prosthesis, said method comprising the steps of:

- a. threading a suture through the opening located at the distal tip of an insertion tool;
- b. securing the said suture through a tunnel located on the distal tip of the distal prosthetic so as to fasten the cylinder of said penile prosthesis to the distal tip of said insertion tool;
- c. positioning the distal tip of the prosthesis cylinder for implantation;
and
- d. pulling the insertion tool and suture back out of the penis.

REMARKS

Claims 1-27 are pending in the application. Claims 2, 3 and 7 have been cancelled and Applicant has amended claims 1, 4, 10, 13 and 26-27 to more clearly define the invention. Page 12, paragraph 0057, of the Specification has been amended to correct a typographical error. No new matter has been added.

Section 112 Rejections

The Examiner rejected claims 3, 4, 7, 10, 24, 26 and 27 under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 3 and 7 have been cancelled. Claims 4 and 10 have been amended to include the specific device that is being set forth. Support for the amendment to claim 4 may be found in the specification at page 11, lines 26-27. Support for the amendment to claim 10

may be found in the specification at page 12, lines 19-21. Claim 24 has been amended so as to make it clear that insertion of the deflated cylinder requires only a small aperture, resulting in a decrease in post operative scarring.

The Examiner indicated that Claims 26 and 27 would be allowable if rewritten or amended to indicate how the prosthesis is secured to the insertion tool. Claims 26 and 27 have been amended to indicate that after threading a suture through the opening located at the distal tip of an insertion tool, the suture is secure either through a tunnel or around the shaft located on the distal tip of the distal prosthetic so as to fasten the cylinder of said penile prosthesis to the distal tip of said insertion tool. Support for the amendments to Claims 26 and 27 may be found at page 11, lines 16-19.

Section 102(b) Rejections

Fishell Reference

Claims 1, 4, 6, 8, 9, 11, 17-19 and 21-25 are rejected under 35 U.S.C. §102(b) as being anticipated by Fishell (4,653,485). The Examiner states that as to claims 1, 6, 9, and 11, Fishell teaches "a device –30- including an elongate body –32- having a handle –38- and a hole –34- or –36- at opposing end –32a- (receptacle), wherein the surface is smooth." As to Claim 17, the Examiner further states that Fishell teaches that "element –10- is a cylinder, the Examiner is taking the inside portion of element –10- surrounding ball –32a- as a cradle, a fluid reservoir is not shown but set forth in column 3, line 33. Element –12- is a means for connecting." The Examiner states that Fishell does not set forth a pump chamber or means for controlling. However, the Examiner takes the position that both are inherently required to fill the chambers.

It is axiomatic that "[f]or a prior art reference to anticipate in terms of 35 USC §102, every element of the claimed invention must be identically shown in a single reference." *In re Bond*, 910 F.2d 831, 832, 15 USPQ 1566, 1567 (Fed. Cir. 1990).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See also MPEP §2131.02.

Applicant respectfully traverses this rejection. As amended Claim 1 is directed to a device for implanting the distal tip of a penile implant prosthesis said device comprising an elongated body having a handle portion at one end and a hole at the opposing end to secure a suture, wherein said handle portion includes an outwardly angled shaft section and linear handle section, and wherein the linear handle section is aligned in spaced and in parallel relation to the axis of the shaft.

The Fishell reference discloses an insertion tool having a handle at one end and two holes at the opposite end. The purpose of the holes is to allow air to enter the internal cylinder and thus preventing a vacuum condition. See column 4, lines 17-24. The Fishell reference does not disclose a device having a handle portion that includes an outwardly angled shaft section and linear handle section that is aligned in spaced and in parallel relation to the axis of the shaft nor a single hole at the opposite end to secure a suture. Therefore not every element of Claim 1 is taught in the Fishell reference, as in Applicant's invention as now claimed. Thus, amended Claim 1 of the present invention is now patentably distinguishable from the Fishell reference.

Claim 6 as amended is directed to a device for implanting the proximal tip of a penile implant prosthesis comprising an elongate shaft including a handle at one end and a receptacle at an opposing end, wherein said receptacle is etched with numbers and grooves to permit precise positioning of the prosthesis in the

penis. The Fishell reference does not disclose having a handle that is etched with numbers and grooves to permit precise positioning of the prosthesis in the penis. Therefore not every element of Claim 6 is taught in the Fishell reference. Thus, amended Claim 6 of the present invention is now patentably distinguishable from the Fishell reference.

Claim 17 is directed to a penile prosthesis device wherein the cylinder has a cradle on the distal tip, said cradle allows the insertion of the distal tip of said penile prosthesis, a fluid reservoir and a pump chamber attached to the reservoir chamber. Fishell discloses a cylinder 10, having a cradle –32a that is located on the tip of the insertion tool 30 not on cylinder 10. Therefore not every element (and its associated structural relationship) of Claim 17 is taught in the Fishell reference. With regards to the pump chamber or means for controlling, Applicant submits that inherency is not a proper argument. Even if the products were identical, which Applicants consider it is not factually, Applicant submits that an inherency argument is inappropriate for failing to provide additional extrinsic evidence to support the inherency argument. As stated by the Federal Circuit:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference and that it would be so recognized by persons of ordinary skill.

Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 20 USPQ 2d 1746, 1749-50 (Fed. Cir. 1991). Further, the Federal Circuit has stated that for a 102(b) rejection, all claimed elements must be found in the prior art. See *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 43 USPQ 2d 1481, 1490 (Fed. Cir. 1997). Thus, Claim 17 of the present invention is patentably distinguishable from the Fishell reference.

Since not every element of Claim 1, 6 and 17 is identified in Fishell, pursuant to the rejection under 35 U.S.C. §102(b), the Examiner has not established a *prima facie* case of anticipation and Applicant requests that this rejection must be withdrawn. Claim 4 depends from Claim 1 while Claims 8, 9 and 11 depend from Claim 6 and are therefore believed to be patentable at least for the same reasons that Claims 1 and 6 are patentable. Claims 18, 19, and 21-25 depend from Claim 17 and are believed to be patentable at least for the same reasons that Claim 17 is patentable. Applicant therefore also requests withdrawal of the rejection of Claims 4, 8, 9, 11, 17-19 and 21-25.

Mohamad Reference

The Examiner rejected Claims 6 and 12-16 under 35 U.S.C. §102(b) as being anticipated by Mohamad (5,484,450) in that Mohamad teaches a device as shown in figure 5, including a shaft –120-, handle –110-, and a receptacle –122, which receptacle, which includes a notch –124-. The Examiner further states that as to Claims 13-16, the Applicant attention is invited to figure 1 and column 1 lines 42-54 of Mohamad.

Applicant traverses this rejection. Claim 6 as amended, is directed to a device for inserting the proximal tip of a penile implant prosthesis said device comprising an elongate shaft including a handle at one end and a receptacle at an opposing end, wherein said handle is etched with numbers and grooves to permit precise positioning of the prosthesis in the penis. The Mohamad reference does not disclose a device wherein the handle is etched with numbers and grooves. Therefore not every element of Claim 6 is taught in the Mohamad reference. Thus, Claim 6 of the present invention is patentably distinguishable from the Mohamad reference.

Claim 13 of the present invention is directed to a device for closure of the penile *corpora*, comprising a shaft with a grip or handle portion and a convex shape protective shield member portion which is dimensioned to conform to the

configuration of the prothesis. Figure 1 and column 1 lines 42-54 of the Mohamad reference is directed to a closing instrument found in the prior art consisting of a spoon-like element welded on its side to a rod-shaped element that extends rearwardly and is connected to the handle. The distal end (the end containing the spool-like element) has a V-shaped notch. The prior art cited in the Mohamad reference does not disclose an instrument having a convex shape protective shield member that is dimensioned to conform to the configuration of the prothesis. Therefore not every element of Claim 13 is taught in Figure 1 (prior art) of the Mohamad reference. Thus, Claim 13 of the present invention is patentably distinguishable from Figure 1 of the Mohamad reference.

Since not every element of Claim 6 and 13 is identified in Mohamad or the prior art identified in the Mohamed reference, the rejection under 35 U.S.C. §102 must be withdrawn. Claim 12 depends from Claim 6 and Claims 14-16 depend from Claim 13 and therefore are believed to be patentable at least for the same reasons that Claims 6 and 13 are patentable. Applicant therefore also requests withdrawal of the rejection under §102(b) of Claims 6 and 12-16.

Section 103(a) Rejections

The Examiner rejected Claims 10 and 20 under 35 U.S.C. §103(a) as being unpatentable over Fishell. As to claim 10, the Examiner states that Fishell teaches a device as claimed as set forth above with regard to claim 6 wherein the shaft is .25 inches but the dimension for the end ball is not set forth. The Examiner concludes "in the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art." The Examiner further states, "in the present application the selection of .39 inches diameter for the ball, 3/8 inches, would be slightly larger than .25 inches and would be within the expected range of the ball of Fishell."

Applicant respectfully traverses this rejection and asserts that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. See *In re Vaeck*, 947 F.2d 288, 20 USPQ2d 1448 (Fed. Cir. 1991).

The Examiner's states that the specific information that is needed to support the obviousness rejection is a matter of "obvious design." Applicant asserts that the Examiner has relied on personal or general knowledge and has provided no reasoning why a specific feature is a matter of obvious design and therefore obvious.

In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

Applicant requests that the Examiner provide sufficient reasoning, to substantiate the claim of obvious design choice or an affidavit under Section 1.107(b) with request to any rejection partly based on the Examiner's personal knowledge.

Moreover, Applicant respectfully asserts that the Examiner is incorrect in stating that in the instant case “the selection of .39 inches diameter for the ball, 3/8, would be slightly larger than .25 inches and would be within the expected range for the ball of Fishell.” Claim 10 is depended from claim 6 and further defines the insertion tool (having a handle at one end and a receptacle at the opposite end) as having a receptacle, which at its widest cross-section has a dimension of 1 cm. The claim does not refer to a “ball having a diameter of .39 inches. Therefore the insertion tool of the present invention having receptacle that at its widest cross-section has a dimension of 1 centimeter is not obvious over Fishell.

Regarding Claim 20, the Examiner states that in the absence of showing any criticality in the selected dimension the selection of any appropriate dimension would have been an obvious design expedient to one of ordinary skill in the art. The Examiner concludes that in the present application, the selection of 5mm distance from the distal end of the cradle would have been an obvious design expedient to one of ordinary skill in the art.

Applicant respectfully traverses this rejection and asserts that the Examiner has failed to establish a *prima facie* case of obviousness. As stated above, the Examiner has relied on personal or general knowledge and has provided no reasoning why a specific feature is a matter of obvious design and therefore obvious. Applicant requests that the Examiner provide sufficient reasoning, to substantiate the claim of obvious design choice or an affidavit under Section 1.107(b) with request to any rejection partly based on the Examiner’s personal knowledge.

Furthermore, Claim 20 is depended from Claim 17. Claim 17 is directed to an improved penile prosthesis device comprising: (a) at least one cylinder having said cylinder having a cradle on the distal tip; (b) a fluid containing reservoir; (c) a pump chamber attached to said reservoir chamber; (d) a means for providing

fluid communication between said cylinder and said pump chamber; and (e) a means for controlling fluid communication between said reservoir chamber and said pump chamber; wherein said cradle allows the insertion of the distal tip of said penile prosthesis to be implanted into the glans penis without puncturing said glans penis.

The penile prosthesis of the present invention is patentably distinguishable from the stiffener cylinder as disclosed in the Fishell reference. The Fishell reference does not disclose a cradle that allows the insertion of the distal tip of said penile prosthesis to be implanted into the glans penis without puncturing said glans penis. Therefore the selection of 5mm distance from the distal end of the cradle is not obvious in light of the Fishell reference.

The Examiner rejected claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over Fishell (4,653,485) in view of Thompson (5,643,288). Claims 2 and 3 have been cancelled.

The Examiner rejected claims 5 and 7 under 35 U.S.C. §103(a) as being unpatentable over Fishell (4,653,485) in view of Furlow et al (4,244,370). The Examiner states that Fishell teaches a device as claimed but does not teach measurement calibrated on the device. Furlow et al teaches an implantation device having measurement calibrations –16-. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to include calibrations as taught by Furlow et al with the device of Fishell to gain the advantage of being able to determine the depth of the device as taught by Furlow et al.

Claim 7 has been cancelled. As to Claim 5, Applicant respectfully traverses this rejection. As stated above, the Fishell reference does not teach a device as claimed in the present application. The Furlow reference discloses tools, respectively known as the Scott and Furlow et al. tools, which among other

things are used to introduce a suture-carrying needle into the penile *corpus cavernosa*. The "Furrow Introducer" shoots a long straight needle (the "Keith Needle"), which holds a traction suture to a distal tip of the penile prosthesis cylinder. The markings on the implantation device are used to determine the depth that the barrel has been inserted into a bodily cavity. The marking on the handle of the present invention used to permit precise positioning of the prosthesis in the penis.

There is no specific teaching or suggestion in the cited art to modify any of the Fishell references or to combine the teachings of the references to provide the insertion tool of Claim 5 comprising an handle portion at one end and a hole at the opposing end wherein said handle portion includes an outwardly angled shaft section and linear handle section that is aligned in spaced and in parallel relation to the axis of the shaft, said handle having measurements to permit precise positioning of the prosthesis in the penis by providing the operator with the exact distance of the distal tip inside the penile shaft. (See specification page 8, lines 9-14). Thus, none of these references alone or together teach or suggest all of the claim limitations of claim 5. Moreover, even if combined the Fishell and Furrow references would not result in the instrument of the present invention.

Objections to the Drawings

The Examiner drawings are objected to under 37 CFR §1.83(a) because the tunnel located on the distal tip of the distal prosthetic must be shown.

35 U.S.C. §113 requires that the Applicant furnish a drawing where necessary for the understanding of the subject matter sought to be patented. A patent application does not have to graphically depict every conceivable element of the invention as long as it details the essential factors. See *Ex parte Taylor*, Patent Office Board of Appeals, 66 U.S.P.Q. 366, 367 (1944) (A rejection of the

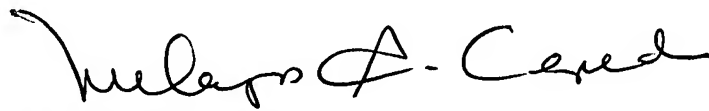
claim for lack of showing in the drawing alone is not tenable.) See also, *Straussler v. United States*, 154 Ct Cl 275, 290 F2d 827, 129 USPQ 480 (1961) (Patent Act does not require the specification to contain illustrated description of every possible device). Applicant asserts that the tunnel located on the distal tip of the prosthetic is one embodiment of the present invention and detailed in the specification at page 12, lines 10-11 such that its illustration is not essential for a proper understanding of the invention. Furthermore, Figure 10 illustrates the use of a suture to secure the distal tip of the prosthetic. Applicant therefore respectfully requests that the Examiner withdraw its objection to the drawings.

In view of the foregoing remarks, Applicants submits that the pending claims particularly define and patentably distinguish the invention over the art of record, and request that the Rejection be withdrawn and that this case is passed to issuance. Should the Examiner believe that further issues remain to be resolved it is requested that she telephone the undersigned in order to provide the Applicant with an opportunity to resolve such issues.

Respectfully submitted,

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